Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents

(Rev. 726, 10-21-05) (Rev. 795, 12-30-05) (Rev. 816, 01-20-06) (Rev. 818, 01-24-06) (Rev. 898, 03-31-06)

- 10- Diagnostic Blood Pressure Monitoring
 - 10.1 Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements
- 11 Wound Treatments
 - 11.1 Electrical Stimulation
 - 11.2 Electromagnetic Therapy
- 12 Smoking and Tobacco-Use Cessation Counseling Services
 - 12.1 HCPCS and Diagnosis Coding
 - 12.2 Carrier Billing Requirements
 - 12.3 FI Billing Requirements
 - 12.4 Remittance Advice (RA) Notices
 - 12.5 Medicare Summary Notices (MSNs)
 - 12.6 Post-Payment Review for Smoking and Tobacco-Use Cessation Counseling Services
 - 12.7 Common Working File (CWF) Inquiry
- 12.8 Provider Access to Smoking and Tobacco-Use Cessation Counseling Services Eligibility Data
- 20- Reserved
- 30 Hyperbaric Oxygen (HBO) Therapy
 - 30.1 Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities
- 40 Sacral Nerve Stimulation
 - 40.1 Coverage Requirements
 - 40.2 Billing Requirements
 - 40.2.1 Healthcare Common Procedural Coding System (HCPCS)

```
40.2.2 – Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595)
```

- 40.2.3 Payment Requirements for Device Codes A4290, E0752 and E0756
- 40.2.4 Payment Requirements for Codes C1767, C1778, C1883 and C1897
- 40.3 Bill Types
- 40.4 Revenue Codes
- 40.5 Claims Editing
- 50 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease
 - 50.1 Coverage Requirements
 - 50.2 Billing Requirements
 - 50.2.1 Part A Intermediary Billing Procedures
 - 50.3 Payment Requirements
 - 50.3.1 Part A Payment Methods
 - 50.3.2 Bill Types
 - 50.3.3 Revenue Codes
 - 50.4 Allowable Codes
 - 50.4.1 Allowable Covered Diagnosis Codes
 - 50.4.2 Allowable Covered Procedure Codes
 - 50.4.3 Healthcare Common Procedure Coding System (HCPCS)
 - 50.5 Ambulatory Surgical Centers
 - 50.6 Claims Editing for Intermediaries
 - 50.7 Remittance Advice Notice for Intermediaries
 - 50.8 Medicare Summary Notices (MSN) Messages for Intermediaries
 - 50.9 Provider Notification
- 60 Coverage and Billing for Home Prothrombin Time (INR) Monitoring for Anticoagulation Management
 - 60.1 Coverage Requirements
 - 60.2 Intermediary Payment Requirements
 - 60.2.1 Part A Payment Methods
 - 60.3 Intermediary Billing Procedures
 - 60.3.1 Bill Types
 - 60.3.2 Revenue Codes
 - 60.4 Intermediary Allowable Codes

- 60.4.1 Allowable Covered Diagnosis Codes
- 60.4.2 Healthcare Common Procedure Coding System (HCPCS) for Intermediaries
- 60.5 Carrier Billing Instructions
 - 60.5.1 Healthcare Common Procedure Coding System (HCPCS) for Carriers
 - 60.5.2 Applicable Diagnosis Code for Carriers
- 60.6 Carrier Claims Requirements
- 60.7 Carrier Payment Requirements
- 60.8 Carrier and Intermediary General Claims Processing Instructions
 - 60.8.1 Remittance Advice Notice
 - 60.8.2 Medicare Summary Notice (MSN) Messages
- 69.0 Qualifying Clinical Trails
 - 69.1 General
 - 69.2 Payment for Qualifying Clinical Trial Services
 - 69.3 Medical Records Documentation Requirements
 - 69.4 Local Medical Review Policy
 - 69.5 Billing Requirements General
 - 69.6 Billing Requirements for Dates of Service on or after January 1, 2002
 - 69.7 Billing Requirements for Services Furnished to Healthy Control Group Volunteers Participating in Diagnostic Trials
 - 69.8 Handling Erroneous Denials of Qualifying Clinical Trial Services
 - 69.9 Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees
 - 69.10 CWF Editing Of Clinical Trial Claims For Managed Care Enrollees
 - 69.11 Resolution of CWF UR 5232 Rejects
- 70 Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial
 - 70.1 Healthcare Common Procedure Coding System (HCPCS) Codes for Carriers
 - 70.2 Applicable Modifier for Islet Cell Transplant Claims for Carriers
 - 70.3 Special Billing and Payment Requirements for Carriers
 - 70.4 Special Billing and Payment Requirements for Intermediaries
 - 70.5 Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

- 80 Billing of the Diagnosis and Treatment of Peripheral Neuropathy with Loss of Protective Sensation in People with Diabetes
 - 80.1 General Billing Requirements
 - 80.2 Applicable HCPCS Codes
 - 80.3 Diagnosis Codes
 - 80.4 Payment
 - 80.5 Applicable Revenue Codes
 - 80.6 Editing Instructions for Fiscal Intermediaries (FIs)
 - 80.7 CWF General Information
 - 80.8 CWF Utilization Edits
- 90 Stem Cell Transplantation
 - 90.1 General
 - 90.2 HCPCS and Diagnosis Coding
 - 90.3 Non-Covered Conditions
 - 90.4 Edits
 - 90.5 Suggested MSN and RA Messages
- 100 Billing Requirements for Expanded Coverage of Cochlear Implantation
 - 100.1 Intermediary Billing Procedures
 - 100.1.1 Applicable Bill Types
 - 100.1.2 Special Billing Requirements for Intermediaries
 - 100.2 Intermediary Payment Requirements
 - 100.3 Carrier Billing Procedures
 - 100.4 Healthcare Common Procedural Coding System (HCPCS)
- 110 Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing
 - 110.1 Coverage Requirements
 - 110.2 Intermediary Billing Requirements
 - 110.3 Bill Types
 - 110.4 Carrier and Intermediary Billing Instructions
 - 110.5 DMERC Billing Instructions
- 120 Presbyopia-Correcting Intraocular Lenses (P-C IOLs) (General Policy Information)
 - 120.1 Payment for Services and Supplies
 - 120.2 Coding and General Billing Requirements
 - 120.3 Provider Notification Requirements

120.4 - Beneficiary Liability

- 130 External Counterpulsation (ECP) Therapy
 - 130.1 Billing and Payment Requirements
 - 130.2 Special Intermediary Billing and Payment Requirements
- 140 Cardiac Rehabilitation Programs
 - 140.1 Coding Requirements
- 150 Billing Requirements for Bariatric Surgery for Morbid Obesity
 - 150.1 General
 - 150.2 HCPCS Coding for Bariatric Procedures
 - 150.3 ICD-9 Diagnosis Codes for Bariatric Surgery
- 150.4 Reasons for Denial and Medicare Summary Notices, Remittance Advice Codes and Claims Adjustment Reason Code Messages
 - 150.5 Fiscal Intermediary Billing Requirements
 - 150.6 ICD-9 Procedure Codes for Bariatric Procedures
 - 150.7 Noncovered ICD-9 Procedure Code for Bariatric Surgery
 - 150.8 Advance Beneficiary Notice and HINN Information\
- 160 PTA for Implanting the Carotid Stent
 - 160.1 Category B IDE Trial Coverage
 - 160.2 Post Approval Trial Coverage
 - 160.3 Carotid Artery Stenting (CAS) With Embolic Protection Coverage

10 - Diagnostic Blood Pressure Monitoring

(Rev. 109, 02-27-04)

10.1 - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements

(Rev. 795, Issued: 12-30-05; Effective: 10-01-04; Implementation: 04-03-06)

A. Coding Applicable to Local Carriers & Fiscal Intermediaries (FIs)

Effective April 1, 2002, a National Coverage Decision was made to allow for Medicare coverage of ABPM for those beneficiaries with suspected "white coat hypertension" (WCH). ABPM involves the use of a non-invasive device, which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by a physician. Suspected "WCH" is defined as: (1) Clinic/office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; (2) At least two documented separate blood pressure measurements taken outside the clinic/office which are < 140/90 mm Hg; and (3) No evidence of end-organ damage. ABPM is not covered for any other uses. Coverage policy can be found in Medicare National Coverage Determinations Manual, Chapter 1, Section 20.19. (www.cms.hhs.gov/masnuals/103 cov determ/ncd103index.asp).

The ABPM must be performed for at least 24 hours to meet coverage criteria. Payment is not allowed for institutionalized beneficiaries, such as those receiving Medicare covered skilled nursing in a facility. In the rare circumstance that ABPM needs to be performed more than once for a beneficiary, the qualifying criteria described above must be met for each subsequent ABPM test.

Effective dates for applicable Common Procedure Coding System (HCPCS) codes for ABPM for suspected WCH and their covered effective dates are as follows:

HCPCS	Definition	Effective Date
93784	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report.	04/01/2002
93786	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.	04/01/2002
93788	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.	01/01/2004

HCPCS Definition Effective Date

93790	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; physician review with interpretation and report.	04/01/2002

In addition, the following diagnosis code must be present:

Diagnosis Code	Description
796.2	Elevated blood pressure reading without diagnosis of hypertension.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for ABPM services are 13X, 23X, 71X, 73X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. The FIs pay for hospital outpatient ABPM services billed on a 13X type of bill with HCPCS 93786 and/or 93788 as follows: (1) Outpatient Prospective Payment System (OPPS) hospitals pay based on the Ambulatory Payment Classification (APC); (2) non-OPPS hospitals (Indian Health Services Hospitals, Hospitals that provide Part B services only, and hospitals located in American Samoa, Guam, Saipan and the Virgin Islands) pay based on reasonable cost, except for Maryland Hospitals which are paid based on a percentage of cost. *Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for ABPM*.

The FIs pay for comprehensive outpatient rehabilitation facility (CORF) ABPM services billed on a 75x type of bill with HCPCS code 93786 and/or 93788 based on the Medicare Physician Fee Schedule (MPFS) amount for that HCPCS code.

The FIs pay for ABPM services for critical access hospitals (CAHs) billed on a 85x type of bill as follows: (1) for CAHs that elected the Standard Method and billed HCPCS code 93786 and/or 93788, pay based on reasonable cost for that HCPCS code; and (2) for CAHs that elected the Optional Method and billed any combination of HCPCS codes 93786, 93788 and 93790 pay based on reasonable cost for HCPCS 93786 and 93788 and pay 115% of the MPFS amount for HCPCS 93790.

The FIs pay for ABPM services for skilled nursing facility (SNF) outpatients billed on a 23x type of bill with HCPCS code 93786 and/or 93788, based on the MPFS.

The FIs accept independent and provider-based rural health clinic (RHC) bills for visits under the all-inclusive rate when the RHC bills on a 71x type of bill with revenue code 052x for providing the professional component of ABPM services. The FIs should not make a separate payment to a RHC for the professional component of ABPM services in addition to the all-inclusive rate. RHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The FIs accept free-standing and provider-based federally qualified health center (FQHC) bills for visits under the all-inclusive rate when the FQHC bills on a 73x type of bill with revenue code 052x for providing the professional component of ABPM services.

The FIs should not make a separate payment to a FQHC for the professional component of ABPM services in addition to the all-inclusive rate. FQHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The FIs pay provider-based RHCs/FQHCs for the technical component of ABPM services when billed under the base provider's number using the above requirements for that particular base provider type, i.e., a OPPS hospital based RHC would be paid for the ABPM technical component services under the OPPS using the APC for code 93786 and/or 93788 when billed on a 13x type of bill.

Independent and free-standing RHC/FQHC practitioners are only paid for providing the technical component of ABPM services when billed to the carrier following the carrier instructions.

C. Carrier Claims

Local carriers pay for ABPM services billed with diagnosis code 796.2 and HCPCS codes 93784 or for any combination of 93786, 93788 and 93790, based on the MPFS for the specific HCPCS code billed.

D. Coinsurance and Deductible

The FIs and local carriers shall apply coinsurance and deductible to payments for ABPM services except for services billed to the FI by FQHCs. For FQHCs only co-insurance applies.

11 - Wound Treatments

(Rev 124a, 03-19-04)

11.1 - Electrical Stimulation

(Rev. 371, Issued 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)

A. Coding Applicable to Carriers & Fiscal Intermediaries (FIs)

Effective April 1, 2003, a National Coverage Decision was made to allow for Medicare coverage of Electrical Stimulation for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the treatment of wounds are not covered by Medicare. Electrical stimulation will not be covered as an initial treatment modality.

The use of electrical stimulation will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electrical stimulation is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days by a physician. Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electrical stimulation must be discontinued when the wound demonstrates a 100% epithelialzed wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1

(http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0281	Electrical Stimulation, (unattended), to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	04/01/2003

Medicare will not cover the device used for the electrical stimulation for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electrical stimulation will not be covered.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for electrical stimulation services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. FIs pay for electrical stimulation services under the Medicare Physician Fee Schedule for a hospital, Comprehensive Outpatient Rehabilitation Facility (CORF), Outpatient Rehabilitation Facility (ORF), Outpatient Physical Therapy (OPT) and Skilled Nursing Facility (SNF).

Payment methodology for independent Rural Health Clinic (RHC), provider-based RHCs, free-standing Federally Qualified Health Center (FQHC) and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for these therapy services.

Payment Methodology for a Critical Access Hospital (CAH) is on a reasonable cost basis unless the CAH has elected the Optional Method and then the FI pays115% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.

In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	Description
420	Physical Therapy

430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *
977, 978	Critical Access Hospital- method II CAH professional services only

^{*} NOTE: As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for these therapy services.

C. Carrier Claims

Carriers pay for Electrical Stimulation services billed with HCPCS codes G0281 based on the MPFS. Claims for Electrical Stimulation services must be billed on Form CMS-1500 or the electronic equivalent following instructions in chapter 12 of this manual (http://www.cms.hhs.gov/manuals/104_claims/clm104c12.pdf).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for these therapy services except for services billed to the FI by FQHCs. For FQHCs, only coinsurance applies.

11.2 - Electromagnetic Therapy

(Rev. 371, Issued 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)

A. HCPCS Coding Applicable to Carriers & Fiscal Intermediaries (FIs)

Effective July 1, 2004, a National Coverage Decision was made to allow for Medicare coverage of electromagnetic therapy for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electromagnetic therapy for the treatment of wounds are not covered by Medicare. Electromagnetic therapy will not be covered as an initial treatment modality.

The use of electromagnetic therapy will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electromagnetic therapy is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days by a physician. Continued treatment with electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electromagnetic therapy must be discontinued when the wound demonstrates a 100% epithelialzed wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1.

(www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0329	ElectromagneticTherapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	07/01/2004

Medicare will not cover the device used for the electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for electromagnetic therapy services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. FIs pay for electromagnetic therapy services under the Medicare Physician Fee Schedule for a hospital, CORF, ORF, and SNF.

Payment methodology for independent (RHC), provider-based RHCs, free-standing FQHC and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

Payment Methodology for a CAH is payment on a reasonable cost basis unless the CAH has elected the Optional Method and then the FI pays pay 115% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.

In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	Description
420	Physical Therapy
430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *

977, 978	Critical Access Hospital- method II CAH professional services only
----------	---

* **NOTE:** As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

C. Carrier Claims

Carriers pay for Electromagnetic Therapy services billed with HCPCS codes G0329 based on the MPFS. Claims for electromagnetic therapy services must be billed on Form CMS-1500 or the electronic equivalent following instructions in chapter 12 of this manual (www.cms.hhs.gov/manuals/104_claims/clm104index.asp).

Payment information for HCPCS code G0329 will be added to the July 2004 update of the Medicare Physician Fee Schedule Database (MPFSD).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for electromagnetic therapy services except for services billed to the FI by FQHCs. For FQHCs only co-insurance applies.

12 - Smoking and Tobacco-Use Cessation Counseling Services

(Rev. 562, Issued: 05-20-05; Effective: 03-22-05; Implementation: 07-05-05)

Background: Effective for services furnished on or after March 22, 2005, a National Coverage Determination (NCD) provides for coverage of smoking and tobacco-use cessation counseling services. Conditions of Medicare Part A and Medicare Part B coverage for smoking and tobacco-use cessation counseling services are located in the Medicare National Coverage Determinations Manual, Publication 100-3, section 210.4.

12.1 - HCPCS and Diagnosis Coding

(Rev. 671, Issued: 09-09-05, Effective: 10-01-05, Implementation: 10-03-05)

The following HCPCS codes should be reported when billing for smoking and tobacco- use cessation counseling services:

 ${f G0375}$ - Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes

Short Descriptor: Smoke/Tobacco counseling 3-10

G0376 - Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes

Short Descriptor: Smoke/Tobacco counseling greater than 10

NOTE: The above G codes will NOT be active in contractors' systems until July 5, 2005. Therefore, contractors shall advise providers to use unlisted code 99199 to bill for smoking and tobacco- use cessation counseling services during the interim period of March 22, 2005, through July 4, 2005, and received prior to July 5, 2005.

On July 5, 2005, contractors' systems will accept the new G codes for services performed on and after March 22, 2005.

Contractors shall allow payment for a medically necessary E/M service on the same day as the smoking and tobacco-use cessation counseling service when it is clinically appropriate. Physicians and qualified non-physician practitioners shall use an appropriate HCPCS code, such as HCPCS 99201–99215, to report an E/M service with modifier 25 to indicate that the E/M service is a separately identifiable service from G0375 or G0376.

Contractors shall only pay for 8 Smoking and Tobacco-Use Cessation Counseling sessions in a 12-month period. The beneficiary may receive another 8 sessions during a second or subsequent year after 11 full months have passed since the first Medicare covered cessation session was performed. To start the count for the second or subsequent 12-month period, begin with the month after the month in which the first Medicare covered cessation session was performed and count until 11 full months have elapsed.

Claims for smoking and tobacco use cessation counseling services shall be submitted with an appropriate diagnosis code. Diagnosis codes should reflect: the condition the patient has that is adversely affected by tobacco use or the condition the patient is being treated for with a therapeutic agent whose metabolism or dosing is affected by tobacco use.

NOTE: This decision does not modify existing coverage for minimal cessation counseling (defined as 3 minutes or less in duration) which is already considered to be covered as part of each Evaluation and Management (E/M) visit and is not separately billable.

12.2 - Carrier Billing Requirements

(Rev. 671, Issued: 09-09-05, Effective: 10-01-05, Implementation: 10-03-05)

With the July 2005 quarterly update to the Medicare Physician Fee Schedule, carriers shall accept the above G codes for dates of service performed on and after March 22, 2005. The type of service (TOS) for each of the new codes is 9.

Carriers pay for counseling services billed with codes G0375 and G0376 based on the Medicare Physician Fee Schedule (MPFS). Deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge, which means that charges to the beneficiary may be no more than 115 percent of the allowed amount.

Physicians or qualified non-physician practitioners shall bill the carrier for smoking and tobacco-use cessation counseling services on the Form CMS-1500 or an approved electronic format.

12.3 - FI Billing Requirements

(Rev. 795, Issued: 12-30-05; Effective: 10-01-04; Implementation: 04-03-06)

Effective for dates of service on and after July 5, 2005, FIs shall recognize the HCPCS codes in 12.1 for Smoking and Tobacco-Use Cessation Counseling services.

A. Claims for Smoking and Tobacco-Use Cessation Counseling Services should be submitted on Form CMS-1450 or its electronic equivalent.

The applicable bill types are 12X, 13X, 22X, 23X, 34X, 71X, 73X, 74X, 75X, 83X, and 85X. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for Smoking and Tobacco-Use Cessation Counseling services.

Applicable revenue codes are as follows:

Provider Type	Revenue Code
Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs)	052X
Indian Health Services (IHS)	0510
Critical Access Hospitals (CAHs) Method II	096X, 097X, 098X
All Other Providers	0942

NOTE: When these services are provided by a Clinical Nurse Specialist in the RHC/FQHC setting, they are considered "incident to" and do not constitute a billable visit.

Payment for outpatient services is as follows:

Type of Facility	Method of Payment
Rural Health Centers	All-inclusive rate (AIR) for the encounter
(RHCs)/Federally Qualified	
Health Centers (FQHCs)	
Indian Health Service	All-inclusive rate (AIR)
(IHS)/Tribally owned or operated	
hospitals and hospital- based	
facilities	
IHS/Tribally owned or operated	Medicare Physician Fee Schedule (MPFS)
non-hospital-based facilities	
IHS/Tribally owned or operated	Facility Specific Visit Rate
Critical Access Hospitals (CAHs)	
Hospitals subject to the	Ambulatory Payment Classification (APC)
Outpatient Prospective Payment	
System (OPPS)	
Hospitals not subject to OPPS	Payment is made under current methodologies
Skilled Nursing Facilities (SNFs)	Medicare Physician Fee Schedule (MPFS)
NOTE: Included in <i>P</i> art A PPS	
for skilled patients.	
Comprehensive Outpatient	Medicare Physician Fee Schedule (MPFS)
Rehabilitation Facilities (CORFs)	
Home Health Agencies (HHAs)	Medicare Physician Fee Schedule (MPFS)

Critical Access Hospitals (CAHs)	Method I: Technical services are paid at 101% of reasonable cost. Method II: technical services are paid at 101% of reasonable cost, and Professional services are paid at 115% of the MMPFS Data Base
Maryland Hospitals	Payment is based according to the Health Services Cost Review Commission (HSCRC). That is 94% of submitted charges subject to any unmet deductible, coinsurance, and non-covered charges policies.

NOTE: Inpatient claims submitted with Smoking and Tobacco-Use Cessation Counseling Services are processed under the current payment methodologies.

12.4 - Remittance Advice (RA) Notices

(Rev. 605, Issued: 07-15-05, Effective: 10-01-05, Implementation: 10-03-05)

Contractors shall use the appropriate claim RA(s) when denying payment for smoking and tobacco-use cessation counseling services.

The following messages are used where applicable:

- If the counseling services were furnished before March 22, 2005, use an appropriate RA claim adjustment reason code, such as, 26, "Expenses incurred prior to coverage."
- If the claim for counseling services is being denied because the coverage criteria are not met, use an appropriate reason code, such as, B5, "Payment adjusted because coverage/program guidelines were not met or were exceeded."

If the claim for counseling services is being denied because the maximum benefit has been reached, use an appropriate RA claim adjustment reason code, such as, 119, "Benefit maximum for this time period or occurrence has been reached."

12.5 - Medicare Summary Notices (MSNs)

(Rev. 671, Issued: 09-09-05, Effective: 10-01-05, Implementation: 10-03-05)

When denying claims for counseling services that were performed prior to the effective date of coverage, contractors shall use an appropriate MSN, such as, MSN 21.11, "This service was not covered by Medicare at the time you received it."

When denying claims for counseling services on the basis that the coverage criteria were not met, use an appropriate MSN, such as MSN 21.21, "This service was denied because Medicare only covers this service under certain circumstances."

When denying claims for counseling services that have dates of service exceeding the maximum benefit allowed, use an appropriate MSN, such as MSN 16.25, "Medicare does not pay for this much equipment, or this many services or supplies."

12.6 - Post-Payment Review for Smoking and Tobacco-Use Cessation Counseling Services

(Rev. 562, Issued: 05-20-05; Effective: 03-22-05; Implementation: 07-05-05)

As with any claim, Medicare may decide to conduct post-payment reviews to determine that the services provided are consistent with coverage instructions. Providers must keep patient record information on file for each Medicare patient for whom a Smoking and Tobacco-Use Cessation Counseling claim is made. These medical records can be used in any post-payment reviews and must include standard information along with sufficient patient histories to allow determination that the steps required in the coverage instructions were followed.

12.7 - Common Working File (CWF) Inquiry

(Rev. 818, Issued: 01-24-06; Effective: 04-01-06; Implementation: 04-03-06)

The Common Working File (CWF) maintains the number of smoking and tobacco-use cessation counseling sessions rendered to a beneficiary. By entering the beneficiary's health insurance claim number (HICN), providers have the capability to view the number of sessions a beneficiary has received for this service via inquiry through CWF.

12.8 - Provider Access to Smoking and Tobacco-Use Cessation Counseling Services Eligibility Data

(Rev.)

30 - Hyperbaric Oxygen (HBO) Therapy

(Rev. 187, 05-28-04)

30.1 - Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

(Rev. 187, 05-28-04)

Hyperbaric Oxygen Therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Effective April 1, 2003, a National Coverage Decision expanded the use of HBO therapy to include coverage for the treatment of diabetic wounds of the lower extremities. For specific coverage criteria for HBO Therapy, refer to the National Coverage Determinations Manual, chapter 1, section 20.29.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

I. Billing Requirements for Intermediaries

Claims for HBO therapy should be submitted on Form CMS-1450 or its electronic equivalent.

a. Applicable Bill Types

The applicable hospital bill types are 11X, 13X and 85X.

b. Procedural Coding

- 99183 Physician attendance and supervision of hyperbaric oxygen therapy, per session.
- C1300 Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.

The HCPCS codes are shown in FL 44 of the Form CMS-1450 or the electronic equivalent.

NOTE: Code C1300 is not available for use other than in a hospital outpatient department. In skilled nursing facilities (SNFs), HBO therapy is part of the SNF PPS payment for beneficiaries in covered Part A stays.

For hospital inpatients and critical access hospitals (CAHs) not electing Method I, HBO therapy is reported under revenue code 940 without any HCPCS code. For inpatient services, show ICD-9-CM procedure code 93.59 in FL 80 and 81.

For CAHs electing Method I, HBO therapy is reported under revenue code 940 along with HCPCS code 99183.

c. Payment Requirements for Intermediaries

Payment is as follows:

Intermediary payment is allowed for HBO therapy for diabetic wounds of the lower extremities when performed as a physician service in a hospital outpatient setting and for inpatients. Payment is allowed for claims with valid diagnostic ICD-9 codes as shown above with dates of service on or after April 1, 2003. Those claims with invalid codes should be denied as not medically necessary.

For hospitals, payment will be based upon the Ambulatory Payment Classification (APC) or the inpatient Diagnosis Related Group (DRG). Deductible and coinsurance apply.

Payment to Critical Access Hospitals (electing Method I) is made under cost reimbursement. For Critical Access Hospitals electing Method II, the technical component is paid under cost reimbursement and the professional component is paid under the Physician Fee Schedule.

II. Carrier Billing Requirements

Claims for this service should be submitted on Form CMS-1500 or its electronic equivalent.

The following HCPCS code applies:

• 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.

a. Payment Requirements for Carriers

Payment and pricing information will occur through updates to the Medicare Physician Fee Schedule Database (MPFSDB). Pay for this service on the basis of the MPFSDB. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken, are subject to the Medicare limiting charge.

III. Medicare Summary Notices (MSNs)

Use the following MSN Messages where appropriate:

In situations where the claim is being denied on the basis that the condition does not meet our coverage requirements, use one of the following MSN Messages:

"Medicare does not pay for this item or service for this condition." (MSN Message 16.48)

The Spanish version of the MSN message should read:

"Medicare no paga por este articulo o servicio para esta afeccion."

In situations where, based on the above utilization policy, medical review of the claim results in a determination that the service is not medically necessary, use the following MSN message:

"The information provided does not support the need for this service or item." (MSN Message 15.4)

The Spanish version of the MSN message should read:

"La información proporcionada no confirma la necesidad para este servicio o articulo."

IV. Remittance Advice Notices

Use appropriate existing remittance advice and reason codes at the line level to express the specific reason if you deny payment for HBO therapy for the treatment of diabetic wounds of lower extremities.

40 – Sacral Nerve Stimulation

(Rev. 125, 03-26-04)

A sacral nerve stimulator is a pulse generator that transmits electrical impulses to the sacral nerves through an implanted wire. These impulses cause the bladder muscles to contract, which gives the patient ability to void more properly.

40.1 – Coverage Requirements

(Rev. 125, 03-26-04)

Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.

The following limitations for coverage apply to all indications:

o Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.

- o Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) that are associated with secondary manifestations of the above three indications are excluded.
- o Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- o Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

40.2 – Billing Requirements

(Rev. 125, 03-26-04)

40.2.1 – Healthcare Common Procedural Coding System (HCPCS)

(Rev. 125, 03-26-04)

64561 - Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

64581 - Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

64585 - Revision or removal of peripheral neurostimulator electrodes

64590 - Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling

64595 - Revision or removal of peripheral neurostimulator pulse generator or receiver

A4290 - Sacral nerve stimulation test lead, each

E0752 - Implantable neurostimulator electrodes, each

E0756 - Implantable neurostimulator pulse generator

C1767 - Generator, neurostimulator (implantable)

C1778 - Lead, neurostimulator (implantable)

C1883 - Adaptor/extension, pacing lead or neurostimulator lead (implantable)

C1897 - Lead, neurostimulator test kit (implantable)

NOTE: The "C" codes listed above are only applicable when billing under the hospital outpatient prospective payment system (OPPS). They should be reported in place of codes A4290, E0752 and E0756.

40.2.2 – Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595)

(Rev. 125, 03-26-04)

Payment is as follows:

- o Hospital outpatient departments OPPS
- o Critical access hospital (CAH) Reasonable cost
- o Comprehensive outpatient rehabilitation facility Medicare physician fee schedule (MPFS)
- o Rural health clinics/federally qualified health centers (RHCs/FQHCs) All inclusive rate, professional component only. The technical component is outside the scope of the RHC/FQHC benefit. Therefore, the provider of that technical service bills their carrier on Form CMS-1500 and payment is made under the MPFS. For provider-based RHCs/FQHCs payment for the technical component is made as indicated above based on the type of provider the RHC/FQHC is based with.

Deductible and coinsurance apply.

40.2.3 – Payment Requirements for Device Codes A4290, E0752 and E0756

(Rev. 125, 03-26-04)

Payment is made on a reasonable cost basis when these devices are implanted in a CAH.

40.2.4 – Payment Requirements for Codes C1767, C1778, C1883 and C1897

(Rev. 125, 03-26-04)

Only hospital outpatient departments report these codes. Payment is made under OPPS.

40.3 – **Bill Types**

(Rev. 795, Issued: 12-30-05; Effective: 10-01-04; Implementation: 04-03-06)

The applicable bill types for test stimulation procedures are 13X, 71X, 73X, 75X and 85X.

The RHCs and FQHCs bill you under bill type 71X and 73X for the professional component. The technical component is outside the scope of the RHC/FQHC benefit. The provider of that technical service bills their carrier on Form CMS-1500 or electronic equivalent.

The technical component for a provider-based RHC/FQHC is typically furnished by the provider. The provider of that service bills you under bill type 13X, or 85X as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services.) *Effective 4/1/06*, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for test stimulation procedures.

The applicable bill types for implantation procedures and devices are 11X, 13X, and 85X.

40.4 – Revenue Codes

(Rev. 125, 03-26-04)

The applicable revenue code for the test procedures is 920 except for RHCs/FQHCs who report these procedures under revenue code 521.

Revenue codes for the implantation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). Therefore, instruct your hospitals to report these implantation procedures under the revenue center where they are performed.

The applicable revenue code for the device codes C1767, C1778, C1883 and C1897, provided in a hospital outpatient department is 272, 274, 275, 276, 278, 279, 280, 289, 290 or 624 as appropriate. The applicable revenue code for device codes A4290, E0752 and E0756 provided in a CAH is 290.

40.5 – Claims Editing

(Rev. 125, 03-26-04)

Nationwide claims processing edits for pre or post payment review of claim(s) for sacral nerve stimulation are not being required at this time. Contractors may develop local medical review policy and edits for such claim(s).

50 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

(Rev. 128, 03-26-04)

Deep brain stimulation (DBS) refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. These DBS electrodes are stereotactically placed within targeted nuclei on one (unilateral) or both (bilateral) sides of the brain. There are currently three targets for DBS -- the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi).

Essential tremor (ET) is a progressive, disabling tremor most often affecting the hands. ET may also affect the head, voice and legs. The precise pathogenesis of ET is unknown. While it may start at any age, ET usually peaks within the second and sixth decades. Beta-adrenergic blockers and anticonvulsant medications are usually the first line treatments for reducing the severity of tremor. Many patients, however, do not adequately respond or cannot tolerate these medications. In these medically refractory ET patients, thalamic VIM DBS may be helpful for symptomatic relief of tremor.

Parkinson's disease (PD) is an age-related progressive neurodegenerative disorder involving the loss of dopaminergic cells in the substantia nigra of the midbrain. The disease is characterized by tremor, rigidity, bradykinesia and progressive postural instability. Dopaminergic medication is typically used as a first line treatment for reducing the primary symptoms of PD. However, after prolonged use, medication can become less effective and can produce significant adverse events such as dyskinesias and other motor function complications. For patients who become unresponsive to medical treatments and/or have intolerable side effects from medications, DBS for symptom relief may be considered.

50.1 – Coverage Requirements

(Rev. 128, 03-26-04)

Effective on or after April 1, 2003, Medicare will cover unilateral or bilateral thalamic VIM DBS for the treatment of ET and/or Parkinsonian tremor and unilateral or bilateral STN or GPi DBS for the treatment of PD only under the following conditions:

- 1. Medicare will only consider DBS devices to be reasonable and necessary if they are Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.
- 2. For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
 - a. Diagnosis of essential tremor (ET) based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia)) which is of a tremor- dominant form.
 - b. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.
 - c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.
 - 3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
 - a. Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).
 - b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
 - c. L-dopa responsive with clearly defined "on" periods.
 - d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
 - e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

The DBS is not reasonable and necessary and is not covered for ET or PD patients with any of the following:

1. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.

- 2. Cognitive impairment, dementia or depression which would be worsened by or would interfere with the patient's ability to benefit from DBS.
- 3. Current psychosis, alcohol abuse or other drug abuse.
- 4. Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.
- 5. Previous movement disorder surgery within the affected basal ganglion.
- 6. Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.

Patients who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.

The DBS should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants which may adversely affect or be affected by the DBS system.

For DBS lead implantation to be considered reasonable and necessary, providers and facilities must meet all of the following criteria:

- 1. Neurosurgeons must: (a) be properly trained in the procedure; (b) have experience with the surgical management of movement disorders, including DBS therapy; and (c) have experience performing stereotactic neurosurgical procedures
- 2. Operative teams must have training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device.
- 3. Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.
- 4. Hospital medical centers must have: (a) brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s); (b) operating rooms with all necessary equipment for stereotactic surgery; and (c) support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

50.2 – Billing Requirements

(Rev. 128, 03-26-04)

50.2.1 – Part A Intermediary Billing Procedures

(Rev. 128, 03-26-04)

This procedure can be two fold. Implantation of the electrodes is performed in a hospital inpatient setting. Implantation of the pulse generator can be performed in an outpatient department.

50.3 - Payment Requirements

(Rev. 128, 03-26-04)

50.3.1 – Part A Payment Methods

(Rev. 128, 03-26-04)

Payment for the inpatient procedure is under Diagnostic Related Group (DRG). The outpatient procedure is outpatient prospective payment system. For critical access hospitals (CAH), the inpatient stay is on reasonable cost and the outpatient procedures are also based on reasonable cost.

50.3.2 – **Bill Types**

(Rev. 128, 03-26-04)

11X, 12X, 13X, 83X, 85X

50.3.3 – Revenue Codes

(Rev. 128, 03-26-04)

Revenue codes for implementation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). The codes to report the pulse generator and/or electrodes are 270, 278, 279.

For CAHs that choose method II, use revenue code 98X for the professional component only.

50.4 – Allowable Codes

(Rev. 128, 03-26-04)

50.4.1 – Allowable Covered Diagnosis Codes

(Rev. 128, 03-26-04)

Deep Brain Stimulation is covered for the following ICD-9-CM diagnosis codes:

332.0 - Parkinson's disease, with paralysis agitans

333.1 – Essential and other specified forms of tremor

50.4.2 – Allowable Covered Procedure Codes

(Rev. 128, 03-26-04)

The following procedure codes may be present:

02.93 – Implantation of intracranial neurostimulator, encompasses the component parts of the surgery that include tunneling to protect the wiring and the initial creation of a pocket for the insertion of the electrical unit into the chest wall

86.09 – Other incision of skin and subcutaneous tissue, to reflect the creation of a pocket for the battery device

86.99 – Other operations on skin and subcutaneous tissue, for the tunneling of the wire connectors

50.4.3 – Healthcare Common Procedure Coding System (HCPCS) (Rev. 128, 03-26-04)

The following HCPCS codes are available for use when billing for covered deep brain stimulation:

- E0752 Implantable Neurostimulator Electrode, Each
- E0756 Implantable Neurostimulator Pulse Generator
- Twist drill, burr hole, craniectomy for stereotactic implantation of one neurostimulator array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray)
- 61880 Revision or removal of intracranial neurostimulator electrodes
- Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
- Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
- 61888 Revision or removal of cranial neurostimulator pulse generator or receiver
- 95961 Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of physician attendance
- Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of physician attendance (List separately in addition to code for primary procedure) (Use 95962 in conjunction with code 95961)
- 95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient

compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

95973 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve); complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, additional 30 minutes after hour (List separately in addition to code for primary procedure) (Use 95973 in conjunction with code 95972)

50.5 – Ambulatory Surgical Centers

(Rev. 128, 03-26-04)

The following HCPCS codes are approved for billing in Ambulatory Surgical Centers:

- Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array ASC Payment Group 02
- Revision or removal of cranial neurostimulator pulse generator or receiver ASC Payment Group 01

NOTE: Pulse generator is payable in an ASC; implantation of electrodes are not.

50.6 – Claims Editing for Intermediaries

(Rev. 128, 03-26-04)

We do not require nationwide standard system claims processing edits for pre and post payment review of claim(s) at this time. However, carriers and intermediaries may create local claims processing edits for the requirements listed above.

50.7 – Remittance Advice Notice for Intermediaries

(Rev. 128, 03-26-04)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason if you deny payment for DBS. If denying services as furnished before April 1, 2003, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

50.8 - Medicare Summary Notice (MSN) Messages for Intermediaries (Rev. 128, 03-26-04)

Use the following MSN messages where appropriate:

If a claim for DBS is denied because the service was performed prior to April 1, 2003, use the MSN message:

"This service was not covered by Medicare at the time you received it." (MSN Message 21.11)

The Spanish version of the MSN message should read:

"Este servicio no estaba cubierto por Medicare cuando usted lo recibió." (MSN Message 21.11)

50.9 – Provider Notification

(Rev. 128, 03-26-04)

Contractors should notify providers of this new national coverage in their next regularly scheduled bulletin, on their Web site within 2 weeks, and in routinely scheduled training sessions.

60 – Coverage and Billing for Home Prothrombin Time (INR) Monitoring for Anticoagulation Management

(Rev. 216, 06-25-04)

Use of the International Normalized Ratio (INR) allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals.

60.1 – Coverage Requirements

(Rev. 216, 06-25-04)

For services furnished on or after July 1, 2002, Medicare will cover the use of home prothrombin time (INR) monitoring for anticoagulation management for patients with mechanical heart valves on warfarin. The monitor and the home testing must be prescribed by a physician and the following patient requirements must be met:

- Must have been anticoagulated for at least three months prior to use of the home INR device;
- Must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
- Self testing with the device is limited to a frequency of once per week.

60.2 – Intermediary Payment Requirements

(Rev. 216, 06-25-04)

60.2.1 – Part A Payment Methods

(Rev. 216, 06-25-04)

Payment is as follows:

- Hospital outpatient departments Outpatient Prospective Payment System (OPPS)
- Critical Access Hospital (CAH) Reasonable cost or Medicare Physician Fee Schedule (MPFS)

Deductible and coinsurance apply.

60.3 – Intermediary Billing Procedures

(Rev. 216, 06-25-04)

60.3.1 – **Bill Types**

(Rev. 216, 06-25-04)

The applicable bill types are 13X and 85X.

60.3.2 – Revenue Codes

(Rev. 216, 06-25-04)

Hospitals may report these services under revenue code 920 or they may report HCPCS codes G0248 and G0249 under the revenue center where they are performed.

60.4 – Intermediary Allowable Codes

(Rev. 216, 06-25-04)

60.4.1 – Allowable Covered Diagnosis Codes

(Rev. 216, 06-25-04)

The applicable diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

NOTE: Porcine valves are not covered, so Medicare will not make payment on Home INR Monitoring for patients with porcine valves.

60.4.2 – Healthcare Common Procedural Coding System (HCPCS) for Intermediaries

(Rev. 216, 06-25-04)

G0248: Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient ability to perform testing.

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.

Short Description: Provide test material, equipm

60.5 – Carrier Billing Instructions

(Rev. 216, 06-25-04)

60.5.1 - Healthcare Common Procedural Coding System (HCPCS) for Carriers

(Rev. 216, 06-25-04)

G0248 TOS (**Type of Service**): Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient ability to perform testing.

Short Description: Demonstrate use home INR mon

G0249 TOS (**Type of Service**): Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.

Short Description: Provide test material, equipm

G0250 TOS (**Type of Service**): Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service)

Short Description: MD review interpret of test

60.5.2 – Applicable Diagnosis Code for Carriers

(Rev. 216, 06-25-04)

ICD-9 V43.3, Organ or tissue replaced by other means; heart valve, applies.

60.6 – Carrier Claims Requirements

(Rev. 216, 06-25-04)

Note this test is not covered as durable medical equipment. Therefore, claims submitted to DMERCs will not be paid. It is covered under the physician fee schedule. Also note that the cost of the device and supplies is included in the payment for G0249 and therefore not separately billed to Medicare. Additionally, for G0250, since this code descriptor is per 4 tests, this code should only be billed no more than once every 4 weeks.

60.7 – Carrier Payment Requirements

(Rev. 216, 06-25-04)

Payment and pricing information will be on the July update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for INR on the basis of the MPFS. Deductible and coinsurance apply.

60.8 – Carrier and Intermediary General Claims Processing Instructions

(Rev. 216, 06-25-04)

60.8.1 – Remittance Advice Notice

(Rev. 216, 06-25-04)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason if you deny payment for INR. If denying services as furnished before July 1, 2002, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

60.8.2 - Medicare Summary Notice (MSN) Messages

(Rev. 216, 06-25-04)

Use the following MSN messages where appropriate:

If a claim for INR is being denied because the service was performed prior to July 1, 2002, use the MSN message:

"This service was not covered by Medicare at the time you received it." (MSN Message 21.11)

The Spanish version of the MSN message should read:

"Este servicio no estaba cubierto por Medicare cuando usted lo recibio`." (MSN Message 21.11)

69.0 - Qualifying Clinical Trials

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

69.1 - General

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in **all** clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in <u>section 310.1</u> of the National Coverage Determinations Manual.

69.2 - Payment for Qualifying Clinical Trial Services

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, DME fee schedule, reasonable charge, etc.). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

69.3 - Medical Records Documentation Requirements

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information

does not need to be submitted with the claim but must be provided if requested for medical review.

69.4 - Local Medical Review Policy

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Do not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.

69.5 - Billing Requirements – General

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Instruct physicians, suppliers and hospitals to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free of charge by research sponsors may not be billed to Medicare.

69.6 - Billing Requirements for Dates of Service on or after January 1, 2002

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For services furnished on or after January 1, 2002, providers are required to submit the following information depending on the type of service and contractor (fiscal intermediary or carrier) to which they are billing:

Fiscal intermediary	Carrier
Condition code 30 (for all types of service)	QV modifier
ICD-9 diagnosis code V70.7 (as secondary diagnosis for all types of service)	NOTE: Reporting of ICD-9 diagnosis code V70.7 is not required unless section 69.7 applies.
QV modifier (outpatient types of services only)	

69.7 - Billing Requirements for Services Furnished to Healthy Control Group Volunteers Participating in Diagnostic Trials

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Routine costs submitted to carriers for services furnished to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed in the following manner:

• The "QV" procedure code modifier is reported at the line item level.

• Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the primary diagnosis

If the QV modifier is billed and diagnosis code V70.7 is submitted to carriers as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a healthy, control group, diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Routine costs submitted to FIs for services furnished to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed on the in the following manner:

- Condition code 30 (qualifying clinical trial) is reported at the line item level
- Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the secondary diagnosis
- "QV" procedure code modifier (only for outpatient claims submitted to FIs)

Fiscal intermediary	Carrier
Condition code 30 (for all types of service)	QV modifier
ICD-9 diagnosis code V70.7 (as secondary diagnosis for all types of service)	ICD-9 diagnosis code V70.7 (as primary diagnosis)
QV modifier (outpatient types of services only)	

69.8 - Handling Erroneous Denials of Qualifying Clinical Trial Services (Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If a service Medicare covers was billed with the appropriate clinical trial coding but was inadvertently denied (e.g., for medical necessity or utilization) and is subsequently brought to your attention, adjust the denied claim. If the denied services weren't properly coded as clinical trial services, instruct the provider to resubmit the service on a new claim with appropriate clinical trial coding.

69.9 - Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Providers who furnish covered clinical trial services to managed care beneficiaries must be enrolled with Medicare in order to bill on a fee-for-service basis. Providers that wish to bill fee for service but have not enrolled with

Medicare must contact their local carrier, intermediary, regional home health intermediary or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

The clinical trial coding requirements for managed care enrollee claims are the same as those for regular Medicare fee for service claims.

69.10 - CWF Editing Of Clinical Trial Claims For Managed Care Enrollees

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Submit clinical trial services for managed care enrollees to CWF for payment approval. CWF will not reject clinical trial claims for managed care enrollees when all services on the claim transaction record are coded as clinical trial services and the date(s) of service is (are) on or after September 19, 2000. In addition, CWF will not apply Part B deductible to clinical trial claims for managed care enrollees (i.e., CWF will process clinical trial services for managed care enrollees as if the Part B deductible has already been met).

69.11 - Resolution of CWF UR 5232 Rejects

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If you send a claim transaction to CWF that includes both clinical and non-clinical trial services for a managed care enrollee, the entire claim will be rejected with the UR 5232 error code. When you receive a UR 5232 error code split the claim and resubmit the clinical trial portion to CWF. Process the non-clinical trial portion of the rejected claims in the same manner that other non-clinical trial fee for service claims for managed care enrollees are handled.

70 - Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial. See Pub 100-04 (National Coverage Determinations Manual) section 260.3.1 for complete coverage policy.

The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial patient. See Pub 100-04, section 310 for further guidance relative to routine care. All other uses for service will remain non-covered.

70.1 - Healthcare Common Procedure Coding System (HCPCS) Codes for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

G0341: Percutaneous islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Percutaneous islet cell trans

Type of Service: 2

G0342: Laparoscopy for islet cell transplant, includes portal vein catheterization and

infusion

Short Descriptor: Laparoscopy islet cell trans

Type of Service: 2

G0343: Laparotomy for islet cell transplant, includes portal vein catheterization and

infusion

Short Descriptor: Laparotomy islet cell transp

Type of Service: 2

70.2 - Applicable Modifier for Islet Cell Transplant Claims for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier **QV** for all claims for islet cell transplantation and routine follow-up care related to this service.

70.3 - Special Billing and Payment Requirements for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Payment and pricing information will be on the October 2004 update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for islet cell transplants on the basis of the MPFS. Deductible and coinsurance apply for fee-for-service beneficiaries.

70.4 - Special Billing and Payment Requirements for Intermediaries

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

This procedure (ICD-9-CM procedure code 52.85-heterotransplantation of islet cells of pancreas) is covered for the clinical trial in an inpatient hospital setting. The applicable TOB is 11X. The second diagnosis must be V70.7 (examination of participant or control in clinical research). V70.7 alerts the claims processing system that this is a clinical trial. The procedure is paid under inpatient prospective payment system for hospitals with patients in the trial. Deductible and coinsurance apply for fee-for-service beneficiaries.

All other normal inpatient billing practices apply.

70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

CMS will make payment directly on a fee-for service basis for the routine costs of pancreatic islet cell transplants as well as transplantation and appropriate related items and services, for MA beneficiaries participating in an NIH-sponsored clinical trial. MA organizations will not be liable for payment for routine costs of this new clinical trial until MA payments can be appropriately adjusted to take into account the cost of this national coverage decision. Medicare contractors shall make payment on behalf of MA organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and Part B deductibles. MA enrollees will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits.

80 - Billing of the Diagnosis and Treatment of Peripheral Neuropathy with Loss of Protective Sensation in People with Diabetes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Coverage Requirements - Peripheral neuropathy is the most common factor leading to amputation in people with diabetes. In diabetes, peripheral neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Peripheral neuropathy with LOPS, secondary to diabetes, is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule (see 42 C.F.R. §411.15(l)(l)(i)). Foot exams for people with diabetic peripheral neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every 6 months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

80.1 - General Billing Requirements - Follow the general bill review instructions in §3604.

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

The following providers of service may bill you for these services:

Hospitals;

Rural Health Clinic;

Free-Standing Federally Qualified Health Clinic (FQHC);

Outpatient Rehabilitation Facility (ORF);

Comprehensive Outpatient Rehabilitation Facility (CORF); and

Critical Access Hospitals

80.2 - Applicable HCPCS Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

G0245 - Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include:

- 1. The diagnosis of LOPS;
- 2. A patient history;
- 3. A physical examination that consists of at least the following elements:
 - (a) visual inspection of the forefoot, hindfoot, and toe web spaces,
 - (b) evaluation of a protective sensation,
 - (c) evaluation of foot structure and biomechanics,
 - (d) evaluation of vascular status and skin integrity,
 - (e) evaluation and recommendation of footwear, and
- 4. Patient education.
- G0246 Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following:
 - 1. a patient history;
 - 2. a physical examination that includes:
 - (a) visual inspection of the forefoot, hindfoot, and toe web spaces,
 - (b) evaluation of protective sensation,
 - (c) evaluation of foot structure and biomechanics,
 - (d) evaluation of vascular status and skin integrity,
 - (e) evaluation and recommendation of footwear, and
 - 3. patient education.
 - G0247 Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a LOPS to include if present, at least the following:
 - (1) local care of superficial (i.e., superficial to muscle and fascia) wounds;

- (2) debridement of corns and calluses; and
- (3) trimming and debridement of nails.

NOTE: Code G0247 must be billed on the same date of service with either G0245 or G0246 in order to be considered for payment.

The short descriptors for the above HCPCS codes are as follows:

G0245 – INITIAL FOOT EXAM PTLOPS

G0246 – FOLLOWUP EVAL OF FOOT PT LOP

G0247 – ROUTINE FOOTCARE PT W LOPS

80.3 - Diagnosis Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Diagnosis Codes.--Providers should report one of the following diagnosis codes in conjunction with this benefit: 250.60, 250.61, 250.62, 250.63, and 357.2.

80.4 - Payment

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

- Hospital outpatient departments OPPS
- Critical Access Hospital (CAH) Method I -- Reasonable cost; Method II -- Technical reasonable cost, Professional -- 115 percent of the fee schedule
- Comprehensive Outpatient Rehabilitation Facility Medicare physician fee schedule (MPFS)
 - Skilled Nursing Facility MPFS
- Rural Health Clinics/Federally Qualified Health Centers (RHCs/FQHCs) -All inclusive rate.

Deductible and coinsurance apply.

Examples of Payment calculation:

Part B Deductible Met: \$900 (MPFS allowed amount) x 20 percent (co-insurance) = \$720 (Medicare reimbursement). Beneficiary is responsible for \$180.

Part B Deductible Not met: \$900 (MPFS allowed amount) - \$100 (Part B deductible) = \$800 x 20 percent (co-insurance) = \$640 (Medicare reimbursement). Beneficiary is responsible for \$260.

Part B Deductible Met: \$800 (actual charged amount) x 20 percent (co-insurance) = \$640 (Medicare Reimbursement), beneficiary is responsible for \$160 co-insurance.

Part B Deductible Not Met: \$800 (actual charged amount) - \$100 (Part B deductible) = \$700 x 20 percent (co-insurance) = \$560 (Medicare reimbursement). Beneficiary is responsible for \$240, (\$100 Part B deductible and \$140 co-insurance).

Services are paid at 80 percent of the lesser of the fee schedule amount or the actual charges.

This service, when furnished in an RHC/FQHC by a physician or non-physician, is considered an RHC/FQHC service. RHCs/FQHCs bill you under bill type 71X or 73X with revenue code 940 and HCPCS G0245, G0246, and G0247.

Payment should not be made for this service unless the claim contains a related visit code. Therefore, install an edit in your system to assure payment is not made for revenue code 940 unless the claim also contains a visit revenue code (520 or 521).

Applicable Revenue Codes

The applicable revenue code is 940, except for hospitals.

This service can be performed in other revenue centers such as a clinic (510) for hospitals. Therefore, instruct your hospitals to report these procedures under the revenue center where they are performed.

80.5 - Applicable Revenue Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

The applicable revenue code is 940, except for hospitals.

This service can be performed in other revenue centers such as a clinic (510) for hospitals. Therefore, instruct your hospitals to report these procedures under the revenue center where they are performed.

80.6 - Editing Instructions for Fiscal Intermediaries (FIs)

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

<u>Edit 1</u> - Implement diagnosis to procedure code edits to allow payment only for the LOPS codes, G0245, G0246, and G0247 when submitted with one of the diagnosis codes 250.60, 250.61, 250.62, 250.63, or 357.2. Deny these services when submitted without one of the appropriate diagnoses.

Use the same messages you currently use for procedure to diagnosis code denials.

Edit 2 – Deny G0247 if it is not submitted on the same claim as G0245 or G0246.

Use MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

Use RA claim adjustment reason code 107 - Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

80.7 - CWF General Information

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Though G0245 and G0246 have no technical or professional components, for these codes, CWF will post FI claims for bill types 13X, 74X, and 75X as technical, and carrier claims as professional. For bill type 85X with revenue code 940, CWF will post as technical. For 85X bill type with revenue code 98X, (Method II), CWF will post as technical and professional. This will allow both the facility and professional service payments to be approved by CWF for payment when the code and date of service match. Therefore, should a claim from a carrier and an FI be received with the same code and same date of

service for the same beneficiary, the second claim submitted will not be rejected as a duplicate.

Due to the billing and payment methodology of Rural Health Clinics - bill type 71X and Federally Qualified Health Centers - bill type 73X, CWF will post these claims as usual, which will correctly allow claims from these entities that are billed to the FI to reject as duplicates when the HCPCS code, date of service, and beneficiary Health Insurance Claim number are an exact match with a claim billed to a carrier.

Carriers and FIs must react to these duplicate claims as they currently do for any other duplicates.

80.8 - CWF Utilization Edits

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Edit 1 - Should CWF receive a claim from an FI for G0245 or G0246 and a second claim from a carrier for either G0245 or G0246 (or vice versa) and they are different dates of service and less than 6 months apart, the second claim will reject. CWF will edit to allow G0245 or G0246 to be paid no more than every 6 months for a particular beneficiary, regardless of who furnished the service. If G0245 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0245 can be paid again or G0246 can be paid. If G0246 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0246 can be paid again or G0245 can be paid. CWF will not impose limits on how many times each code can be paid for a beneficiary as long as there has been 6 months between each service.

The CWF will return a specific reject code for this edit to the carriers and FIs that will be identified in the CWF documentation. Based on the CWF reject code, the carriers and FIs must deny the claims and return the following messages:

MSN 18.4 -- This service is being denied because it has not been __ months since your last examination of this kind (NOTE: Insert 6 as the appropriate number of months.)

RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for similar procedure within set time frame.

Edit 2

The CWF will edit to allow G0247 to pay only if either G0245 or G0246 has been submitted <u>and accepted as payable</u> on the same date of service. CWF will return a specific reject code for this edit to the carriers and FIs that will be identified in the CWF documentation. Based on this reject code, carriers and FIs will deny the claims and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

RA claim adjustment reason code 107 - Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

Edit 3

Once a beneficiary's condition has progressed to the point where routine foot care becomes a covered service, payment will no longer be made for LOPS evaluation and management services. Those services would be considered to be included in the regular exams and treatments afforded to the beneficiary on a routine basis. The physician or provider must then just bill the routine foot care codes along with the appropriate modifier.

The CWF will edit to reject LOPS codes G0245, G0246, and/or G0247 when on the beneficiary's record it shows that one of the following routine foot care codes were billed and paid within the prior 6 months: 11055, 11056, 11057, 11719, 11720, and/or 11721.

The CWF will return a specific reject code for this edit to the carriers and FIs that will be identified in the CWF documentation. Based on the CWF reject code, the carriers and FIs must deny the claims and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

The RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for similar procedure within set time frame.

90 - Stem Cell Transplantation

(Rev. 776, Issued: 12-06-05, Effective: 11-28-05, Implementation: 01-03-06)

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplantation (AuSCT) must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. See Pub. 100-03, National Coverage Determinations Manual, section 110.8.1, for a complete description of covered and noncovered conditions. The following sections contain claims processing instructions for carrier claims. For institutional claims processing instructions, please refer to Pub. 100-04, chapter 3, section 90.3.

90.1 - General

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

• Allogeneic Stem Cell Transplantation.

Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor's stem cells is obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect.

Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. Services to the donor include physician services, hospital care in connection with screening the stem cell, and ordinary follow-up care.

Autologous Stem Cell Transplantation

Autologous stem cell transplantations is a technique for restoring stem cells using the patient's own previously stored cells. Autologous stem cell transplants are covered for certain specified diagnoses for services rendered on or after April 28, 1989.

90.2 - HCPCS and Diagnosis Coding

(Rev. 526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

Allogeneic Stem Cell Transplantation

- Effective for services performed on or after August 1, 1978:
- -- For the treatment of leukemia or leukemia in remission, providers shall use ICD-9-CM codes 204.00 through 208.91 and HCPCS code 38240.
- -- For the treatment of aplastic anemia, providers shall use ICD-9-CM codes 284.0 through 284.9 and HCPCS code 38240.
 - Effective for services performed on or after June 3, 1985:
- -- For the treatment of severe combined immunodeficiency disease, providers shall use ICD-9-CM code 279.2 and HCPCS code 38240.
- -- For the treatment of Wiskott-Aldrich syndrome, providers shall use ICD-9-CM code 279.12 and HCPCS code 38240.
 - Effective for services performed on or after May 24, 1996:
- -- Allogeneic stem cell transplantation, HCPCS code 38240 is not covered as treatment for the diagnosis of multiple myeloma ICD-9-CM codes 203.00 or 203.01.
- Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services performed on or after April 28, 1989:
- For the treatment of patients with acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA) matched, providers shall use ICD-9-CM code 204.01 lymphoid; ICD-9-CM code 205.01 myeloid; ICD-9-CM code 206.01 monocytic; or ICD-9-CM code 207.01 acute erythremia and erythroleukemia; or ICD-9-CM code 208.01 unspecified cell type and HCPCS code 38241.
- For the treatment of resistant non-Hodgkin's lymphomas for those patients presenting with poor prognostic features following an initial response, providers shall use ICD-9-CM codes 200.00 200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88 or 202.90-202.98 and HCPCS code 38241.

- For the treatment of recurrent or refractory neuroblastoma, providers shall use ICD-9-CM codes Neoplasm by site, malignant, the appropriate HCPCS code and HCPCS code 38241.
- For the treatment of advanced Hodgkin's disease for patients who have failed conventional therapy and have no HLA-matched donor, providers shall use ICD-9-CM codes 201.00 201.98 and HCPCS code **38241**.
- Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services furnished on or after October 1, 2000:
- For the treatment of multiple myeloma (only for beneficiaries who are less than age 78, have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma, and have adequate cardiac, renal, pulmonary and hepatic functioning), providers shall use ICD- 9-CM code 203.00 or 238.6 and HCPCS code 38241.
- For the treatment of recurrent or refractory neuroblastoma, providers shall use appropriate code (see ICD-9-CM neoplasm by site, malignant) and HCPCS code 38241.
- Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan (HDM) together with autologous stem cell transplantation (HDM/AuSCT) is reasonable and necessary for Medicare beneficiaries of any age group for the treatment of primary amyloid light chain (AL) amyloidosis, ICD-9-CM code 277.3 who meet the following criteria:
 - Amyloid deposition in 2 or fewer organs; and,
 - Cardiac left ventricular ejection fraction (EF) greater than 45%.

90.3 - Non-Covered Conditions

(Rev. 526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

Autologous stem cell transplantation is not covered for the following conditions:

- Acute leukemia not in remission (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);
 - Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);
- Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0 through 199.1); or
- Effective for services rendered on or after May 24, 1996 through September 30, 2000, multiple myeloma (ICD-9-CM code 203.00 and 203.01).
- Effective for services on or after October 1, 2000, through March 14, 2005, for Medicare beneficiaries age 64 or older, all forms of amyloidosis, primary and non-primary (ICD-9-CM code 277.3)
- Effective for services on or after 10/01/00, for all Medicare beneficiaries, non-primary amyloidosis (ICD-9-CM code 277.3).

NOTE: Coverage for conditions other than those specifically designated as covered in 90.2 or specifically designated as non-covered in this section will be at the discretion of the individual carrier.

90.4 - Edits

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

NOTE: Coverage for conditions other than those specifically designated as covered in 80.2 or specifically designated as non-covered in this section will be at the discretion of the individual carrier.

Appropriate diagnosis to procedure code edits should be implemented for the covered conditions and services in 90.2

As the ICD-9-CM code 277.3 for amyloidosis does not differentiate between primary and non-primary, carriers should perform prepay reviews on all claims with a diagnosis of ICD-9-CM code 277.3 and a HCPCS procedure code of 38241 to determine whether payment is appropriate.

90.5 - Suggested MSN and RA Messages

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

The contractor shall use an appropriate MSN and RA message such as the following:

MSN - 15.4, The information provided does not support the need for this service or item;

RA - 150, Payment adjusted because the payer deems the information submitted does not support this level of service.

100 – Billing Requirements for Expanded Coverage of Cochlear Implantation

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

Effective for dates of services on and after April 4, 2005, the Centers for Medicare & Medicaid Services (CMS) has expanded the coverage for cochlear implantation to cover moderate-to-profound hearing loss in individuals with hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification. (See Publication 100-03, chapter 1, section 50.3, for specific coverage criteria).

In addition CMS is covering cochlear implantation for individuals with open-set sentence recognition test scores of greater than 40% to less than or equal to 60% correct but only when the provider is participating in, and patients are enrolled in, either:

- A Food and Drug Administration(FDA)-approved category B investigational device exemption (IDE) clinical trial; or
- A trial under the CMS clinical trial policy (see Pub. 100-03, section 310.1); or

A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for national coverage analyses and meeting specific quality standards.

100.1 – Intermediary Billing Procedures

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

100.1.1 – Applicable Bill Types

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

11X, 12X (see note below), 13X, 83X, 85X

NOTE: Surgical procedures are not acceptable on 12x bill types.

100.1.2 – Special Billing Requirements for Intermediaries

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

For inpatient billing:

• The second or subsequent diagnosis code must be V70.7 (examination of participant or control in clinical research). V70.7 alerts the claims processing system that this is a clinical trial.

For inpatient Part B and outpatient bills:

- For patients in an approved clinical trial with hearing test scores greater than 40% to less than or equal to 60% hearing, the QR modifier must be reported with the cochlear implantation device and all other related costs or; (see note below)
- For patients in an approved clinical trial under the clinical trial policy with hearing test scores greater than 60% hearing, the QV modifier must be billed for routine costs.

NOTE: The QR or QV modifier does not need to be applied to HCPCS 92601-92604 or any applicable audiology codes.

100.2 – Intermediary Payment Requirements

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

There are no special payment methods. Existing payment methods shall apply.

100.3 – Carrier Billing Procedures

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

Effective for dates of service performed on and after April 4, 2005, the following applies:

Carriers shall accept claims for cochlear implantation devices and services for beneficiaries with moderate-to-profound hearing loss with hearing test scores equal to or less than 40%.

Carriers shall accept claims for cochlear implantation devices and all related costs for beneficiaries with hearing test scores of greater than 40% to less than or equal to 60% hearing provided in an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial policy, or a prospective, controlled comparative trial approved by CMS that is billed with the QR modifier. The definition of the QR modifier is, "Item or service provided in a Medicare specified study."

Carriers shall accept claims for routine costs pertaining to beneficiaries with hearing test scores of greater than 60% hearing who are in a clinical trial under the clinical trial policy

that is billed with the QV modifier. The definition of the QV modifier is, "Item or service provided as routine care in a Medicare qualifying clinical trial."

Carriers shall accept claims for evaluation and therapeutic services related to cochlear implantation.

NOTE: Modifiers QR or QV do not need to be applied to these services (92601–92604 or any applicable audiology codes).

These services should be billed on an approved electronic claim form or a paper CMS Form 1500.

100.4 – Healthcare Common Procedural Coding System (HCPCS)

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

The following HCPCS codes are some of those available for use when billing for cochlear implantation services and devices provided by audiologists or physicians, and for the services of 92506 and 92507, by speech language pathologists.

69930 – Cochlear device implantation, with or without mastoidectomy

L8614 – Cochlear Device/System

L8619 – Cochlear implant external speech processor, replacement

L7500 – Repair of prosthetic device, hourly rate (excludes V5335 repair of oral laryngeal prosthesis or artificial larynx)

L7510 – Repair of prosthetic device, repair or replace minor parts

92506 – Evaluation of speech, language, voice, communication, auditory processing, and/or aural rehabilitation status

92507 – Treatment of speech, language, voice, communication, and/or auditory processing disorder (includes aural rehabilitation); individual

92601 – Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming

(Codes 92601 and 92603 describe post-operative analysis and fitting of previously placed external devices, connection to the cochlear implant, and programming of the stimulator. Codes 92602 and 92604 describe subsequent sessions for measurements and adjustment of the external transmitter and re-programming of the internal stimulator.)

92602 – Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent programming. (Do not report 92602 in addition to 92601.)

92603 – Diagnostic analysis of cochlear implant, age 7 years or older; with programming

92604 – Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

A complete list of audiology codes can be found in Pub 100-4, chapter 12, section 30.3.

110 – Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. This device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not to be used concurrently with other non-invasive osteogenic devices.

110.1 – Coverage Requirements

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on and after April 27, 2005, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgical intervention. In demonstrating nonunion fractures, CMS expects:

• A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

For further coverage information, please refer to the National Coverage Determinations Manual, Pub. 100-03, chapter 1, section 150.2.

110.2 – Intermediary Billing Requirements

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

The RHHIs will pay for ultrasonic osteogenic stimulators only when services are submitted on type of bills (TOBs) listed under Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 100.3.

Fiscal intermediaries (FIs) must educate hospitals that there are no covered services for Ultrasonic Osteogenic Stimulation for which hospitals can be paid by the FI.

NOTE: Hospitals can not bill for Ultrasonic Osteogenic Stimulators.

110.3 – **Bill Types**

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Only the following TOBs can bill for Ultrasonic Osteogenic Stimulators: 32X, 33X, 34X, which is payable under the DMEPOS Fee Schedule.

NOTE: Ultrasonic Osteogenic Stimulators must be in the patient's home health plan of care if billed on TOBs 32X or 33X.

110.4 – Carrier and Intermediary Billing Instructions

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on or after April 27, 2005, contractors shall allow payment for ultrasonic osteogenic stimulators with the following current procedural terminology (CPT) code:

• 20979 - Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

110.5 – DMERC Billing Instructions

(Rev. 816, Issued: 01-20-06, Effective: 04-27-05, Implementation: 04-03-06)

Effective for dates of service on or after April 27, 2005, DMERCs shall allow payment for ultrasonic osteogenic stimulators with the following HCPCS codes:

E0760 for low intensity ultrasound (include modifier "KF"), or;

E1399 for other ultrasound stimulation (include modifier "KF")

120 - Presbyopia-Correcting Intraocular Lenses (P-C IOLs) (General Policy Information)

(Rev. 801, Issued: 12-30-05; Effective: 01-01-06; Implementation: 01-03-06)

Per CMS Ruling 05-01, issued May 3, 2005, Medicare will allow beneficiaries to pay additional charges associated with insertion of a P-C IOL following the extraction of a cataractous lens.

- Presbyopia is a type of age-associated refractive error that results in progressive loss of the focusing power of the lens of the eye, causing difficulty seeing objects at near distance, or close-up. Presbyopia occurs as the natural lens of the eye becomes thicker and less flexible with age.
- A presbyopia-correcting IOL is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) following cataract extraction that is intended to provide near, intermediate and distance vision without the need for eyeglasses or contact lenses.

120.1 - Payment for Services and Supplies

(Rev. 801, Issued: 12-30-05; Effective: 01-01-06; Implementation: 01-03-06)

For an IOL inserted following removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the hospital Outpatient Prospective Payment System (OPPS) or the Inpatient Prospective Payment System (IPPS), respectively; or in a Medicare-approved ambulatory surgical center (ASC) that is paid under the ASC fee schedule:

- Medicare does not make separate payment to the hospital or ASC for an IOL inserted subsequent to extraction of a cataract. Payment for the IOL is packaged into the payment for the surgical cataract extraction/lens replacement procedure.
- Any person or ASC, who presents or causes to be presented a bill or request for payment for an IOL inserted during or subsequent to cataract surgery for which payment is made under the ASC fee schedule, is subject to a civil money penalty.

For a presbyopia-correcting IOL inserted subsequent to removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the OPPS or the IPPS, respectively; or in a Medicare-approved ASC that is paid under the ASC fee schedule:

- The facility shall bill for the removal of a cataract with insertion of a conventional IOL, regardless of whether a conventional or presbyopia-correcting IOL is inserted. When a beneficiary receives a presbyopia-correcting IOL following removal of a cataract, hospitals and ASCs shall report the same CPT code that is used to report removal of a cataract with insertion of a conventional IOL. Physicians, hospitals and ASCs may also report an additional HCPCS code, V2788to indicate any additional charges that accrue when a P-C IOL is inserted in lieu of a conventional IOL. See Section 120.2 for coding guidelines.
- There is no Medicare benefit category that allows payment of facility charges for services and supplies required to insert and adjust a presbyopia-correcting IOL following removal of a cataract that exceed the facility charges for services and supplies required for the insertion and adjustment of a conventional IOL.
- There is no Medicare benefit category that allows payment of facility charges for subsequent treatments, services and supplies required to examine and monitor the beneficiary who receives a presbyopia-correcting IOL following removal of a cataract that exceeds the facility charges for subsequent treatments, services and supplies required to examine and monitor a beneficiary after cataract surgery followed by insertion of a conventional IOL.

A - For a P-C IOL inserted in a physician's office

- A physician shall bill for a conventional IOL, regardless of a whether a conventional or presbyopia-correcting IOL is inserted (see section 120.2, General Billing Requirements)
- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a presbyopia-correcting IOL following removal of a cataract that exceed the physician charges for services and supplies for the insertion and adjustment of a conventional IOL.
- There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, service and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of a presbyopia-correcting IOL that exceed physician charges for services and supplies to examine and monitor a beneficiary following removal of a cataract with insertion of a conventional IOL.

B - For a P-C IOL inserted in a hospital

- A physician may not bill Medicare for a presbyopia-correcting IOL inserted during a cataract procedure performed in a hospital setting because the payment for the lens is included in the payment made to the facility for the surgical procedure.
- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a presbyopia-correcting IOL following removal of a cataract that exceed the physician charges for services and supplies required for the insertion of a conventional IOL.

C - For a P-C IOL inserted in an Ambulatory Surgical Center

- Refer to Chapter 14, Section 40.3 for complete guidance on payment for P-C IOL in Ambulatory Surgical Centers.

120.2 - Coding and General Billing Requirements

(Rev. 801, Issued: 12-30-05; Effective: 01-01-06; Implementation: 01-03-06)

Physicians and hospitals must report one of the following Current Procedural Terminology (CPT) codes on the claim:

- 66982 Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage.
- 66983 Intracapsular cataract with insertion of intraocular lens prosthesis (one stage procedure)
- 66984 Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)
- 66985 Insertion of intraocular lens prothesis (secondary implant), not associated with concurrent cataract extraction
 - 66986 Exchange of intraocular lens

In addition, physicians inserting a P-C IOL in an office setting may bill code V2632 (posterior chamber intraocular lens) for the IOL.Medicare will make payment for the lens based on reasonable cost for a conventional IOL. Place of Service (POS) = 11.

Effective for dates of service on and after January 1, 2006, physician, hospitals and ASCs may also bill the non-covered charges related to the presbyopia-correcting function of the IOL using HCPCS code V2788. The type of service indicator for the non-covered billed charges is Q. (The type of service is applied by the Medicare carrier and not the provider.)

When denying the non-payable charges submitted with V2788, contractors shall use an appropriate Medical Summary Notice (MSN) such as 16.10 (Medicare does not pay for this item or service) and an appropriate claim adjustment reason code such as 96 (non-covered charges) for claims submitted with the non-payable charges.

Hospitals and physicians shall bill the following CPT codes for evaluation and management services associated with the services following cataract extraction surgery:

- 92002 Opthalmological services; medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient
- 92004 Opthalmological services; medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient

- 92012 Opthalmological services; medical examination and evaluation with initiation or continuation of diagnostic and treatment program; intermediate established patient
- 92014 Opthalmological services; medical examination and evaluation with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, one or more services

A - Applicable Bill Types

The hospital applicable bill types are 12X, 13X, 83X and 85X.

B - Other Special Requirements for Hospitals

Hospitals shall continue to pay Critical Access Hospitals (CAHs) method 2 claims under current payment methodologies for conditional IOLs.

120.3 - Provider Notification Requirements

(Rev. 801, Issued: 12-30-05; Effective: 01-01-06; Implementation: 01-03-06)

When a beneficiary requests insertion of a presbyopia-correcting IOL instead of a conventional IOL following removal of a cataract:

- Prior to the procedure to remove a cataractous lens and insert a presbyopia-correcting lens, the facility and the physician must inform the beneficiary that Medicare will not make payment for services that are specific to the insertion, adjustment or other subsequent treatments related to the presbyopia-correcting functionality of the IOL.
- The presbyopia-correcting functionality of a presbyopia-correcting IOL does not fall into a Medicare benefit category, and, therefore, is not covered. Therefore, the facility and physician are not required to provide an Advanced Beneficiary Notice to beneficiaries who request a presbyopia-correcting IOL.
- Although not required, CMS strongly encourages facilities and physicians to issue a Notice of Exclusion from Medicare Benefits to beneficiaries in order to clearly identify the non-payable aspects of a presbyopia-correcting IOL insertion. This notice may be found in English at http:\\cms.hhs.gov/medicare/bni/20007_English.pdf

Spanish language at: http://cms.hhs.gov/medicare/bni/20007_Spanish.pdf.

120.4 - Beneficiary Liability

(Rev. 801, Issued: 12-30-05; Effective: 01-01-06; Implementation: 01-03-06)

When a beneficiary requests insertion of a presbyopia-correcting IOL instead of a conventional IOL following removal of a cataract and that procedure is performed, the beneficiary is responsible for payment of facility and physician charges for services and supplies attributable to the presbyopia-correcting functionality of the presbyopia-correcting IOL:

• In determining the beneficiary's liability, the facility and physician may take into account any additional work and resources required for insertion, fitting, vision acuity testing, and monitoring of the presbyopia-correcting IOL that exceed the work and resources attributable to insertion of a conventional IOL.

- The physician and the facility may not charge for cataract extraction with insertion of a presbyopia-correcting IOL unless the beneficiary requests this service.
 - The physician and the facility may not require the beneficiary to request a presbyopia-correcting IOL as a condition of performing a cataract extraction with IOL insertion.

130 - External Counterpulsation (ECP) Therapy

(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory medical and/or surgical therapy. Effective for dates of service July 1, 1999, and after, Medicare will cover ECP when its use is in patients with stable angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass, because:

- Their condition is inoperable, or at high risk of operative complications or post-operative failure;
 - Their coronary anatomy is not readily amenable to such procedures; or
 - They have co-morbid states that create excessive risk.

(Refer to Publication 100-03, section 20.20 for further coverage criteria.)

130.1 - Billing and Payment Requirements

(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Effective for dates of service on or after January 1, 2000, use HCPCS code G0166 (External counterpulsation, per session) to report ECP services. The codes for external cardiac assist (92971), ECG rhythm strip and report (93040 or 93041), pulse oximetry (94760 or 94761) and plethysmography (93922 or 93923) or other monitoring tests for examining the effects of this treatment are not clinically necessary with this service and should not be paid on the same day, unless they occur in a clinical setting not connected with the delivery of the ECP. Daily evaluation and management service, e.g., 99201-99205, 99211-99215, 99217-99220, 99241-99245, cannot be billed with the ECP treatments. Any evaluation and management service must be justified with adequate documentation of the medical necessity of the visit. Deductible and coinsurance apply.

130.2 - Special Intermediary Billing and Payment Requirements (Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Payment is made to hospitals for the facility costs it incurs under Part B on a reasonable cost basis. Payment is also made to PPS-exempt hospitals for the facility costs it incurs on a reasonable cost basis. Deductible and coinsurance apply.

Applicable bill types are 12X, 13X, 83X or 85X.

140 - Cardiac Rehabilitation Programs

(Rev.)

```
140.1 - Coding Requirements
(Rev.)
150 - Billing Requirements for Bariatric Surgery for Morbid Obesity
(Rev.)
150.1 - General
(Rev.)
150.2 - HCPCS Coding for Bariatric Procedures
(Rev.)
150.3 - ICD-9 Diagnosis Codes for Bariatric Surgery
(Rev.)
150.4 - Reasons for Denial and Medicare Summary Notices, Remittance
Advide Codes and Claims Adjustment Reason Code Messages
(Rev.)
150.5 - Fiscal Intermediary Billing Requirements
(Rev.)
150.6 - ICD-9 Procedure Codes for Bariatric Procedures
(Rev.)
150.7 - Noncovered ICD-9 Procedure Code for Bariatric Surgery
(Rev.)
```

150.8 - Advance Benficiary Notice and HINN Information

(Rev.)

160 – PTA for Implanting the Carotid Stent
(Rev.)

160.1 – Category B IDE Trial Coverage
(Rev.)

160.2 – Post Approval Trial Coverage
(Rev.)

160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage

(Rev.)